



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 October 2025
EMADOC-1700519818-2580931
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): mannitol (all indications apart from cystic fibrosis)

EURD list No. PSUSA/00010005/202502



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Aridol Pulver zur Inhalation	SE/H/0711/001	68119.00.00	PHARMAXIS EUROPE LIMITED	DE
Aridol Pulver zur Inhalation	SE/H/0711/001	68119.00.00	PHARMAXIS EUROPE LIMITED	DE
MANNITOL- INFUSIONSLÖSUNG 15 Mannitol 15%	not available	3000207.00.00	BURG PHARMA GMBH	DE
MANNITOL- INFUSIONSLÖSUNG 15 Mannitol 15%	not available	3000207.00.00	BURG PHARMA GMBH	DE
MANNITOL- INFUSIONSLÖSUNG 15 Mannitol 15%	not available	3000207.00.00	BURG PHARMA GMBH	DE
MANNITOL- INFUSIONSLÖSUNG 15 Mannitol 15%	not available	3000207.00.00	BURG PHARMA GMBH	DE
MANNITOL- INFUSIONSLÖSUNG 15 Mannitol 15%	not available	3000207.00.00	BURG PHARMA GMBH	DE
MANNITOL- INFUSIONSLÖSUNG 15 Mannitol 15%	not available	3000207.00.00	BURG PHARMA GMBH	DE
Osmohale, inhalationspulver, hård kapsel	SE/H/0711/001	40400	PHARMAXIS EUROPE LIMITED	DK
Osmohale, inhalationspulver, hård kapsel	SE/H/0711/001	40400	PHARMAXIS EUROPE LIMITED	DK
Osmohale, polvo para inhalación (cápsulas duras)	SE/H/0711/001	69945	PHARMAXIS EUROPE LIMITED	ES
Osmohale, polvo para inhalación (cápsulas duras)	SE/H/0711/001	69945	PHARMAXIS EUROPE LIMITED	ES
Aridol inhalaatiojauhe, kapseli, kova	SE/H/0711/001	22940	PHARMAXIS EUROPE LIMITED	FI

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Aridol inhalaatiojauhe, kapseli, kova	SE/H/0711/001	22940	PHARMAXIS EUROPE LIMITED	FI
Aridol inhalationspulver, hårda kapslar	SE/H/0711/001	22940	PHARMAXIS EUROPE LIMITED	FI
Aridol inhalationspulver, hårda kapslar	SE/H/0711/001	22940	PHARMAXIS EUROPE LIMITED	FI
MANNITOL LAVOISIER 20 POUR CENT, solution pour perfusion	not available	34009 560 729 6 5	LABORATOIRES CHAIX ET DU MARAIS	FR
MANNITOL LAVOISIER 20 POUR CENT, solution pour perfusion	not available	34009 344 874 1 5	LABORATOIRES CHAIX ET DU MARAIS	FR
Osmohale inhalation powder, hard capsule	SE/H/0711/001	PA 22655/001/001	PHARMAXIS EUROPE LIMITED	IE
Osmohale inhalation powder, hard capsule	SE/H/0711/001	PA 22655/001/001	PHARMAXIS EUROPE LIMITED	IE
Osmohale, inhalatiepoeder in harde capsules	SE/H/0711/001	RVG 34641	PHARMAXIS EUROPE LIMITED	NL
Osmohale, inhalatiepoeder in harde capsules	SE/H/0711/001	RVG 34641	PHARMAXIS EUROPE LIMITED	NL
Aridol inhalasjonspulver, hard kapsel	SE/H/0711/001	06-4599	PHARMAXIS EUROPE LIMITED	NO
Aridol inhalasjonspulver, hard kapsel	SE/H/0711/001	06-4599	PHARMAXIS EUROPE LIMITED	NO
Aridol inhalationspulver, hård kapsel.	SE/H/0711/001	22708	PHARMAXIS EUROPE LIMITED	SE
Aridol inhalationspulver, hård kapsel.	SE/H/0711/001	22708	PHARMAXIS EUROPE LIMITED	SE
Osmohale inhalation powder, hard capsule	SE/H/0711/001	PL 50608/0001	PHARMAXIS EUROPE LIMITED	XI
Osmohale inhalation powder, hard capsule	SE/H/0711/001	PL 50608/0001	PHARMAXIS EUROPE LIMITED	XI